

Notice of Allowability

Application No.

09/581,106

Examiner

Joyce Tung

Applicant(s)

AUSUBEL ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/06/2004.
2. ☒ The allowed claim(s) is/are claims 1, 3-10, and 12-20 (final claims 1-18).
3. ☒ The drawings filed on 30 January 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

REASONS FOR ALLOWANCE

The applicant's response filed May 6, 2004 to the Office action has been entered. Claims 1, 3-10 and 12-20 are pending.

1. The following is an examiner's statement of reasons for allowance:

Concerning claims 1, 3-10 and 12-20, no prior art has been found teaching or suggesting the method and the kit for determining whether a nucleic acid sequence comprising a particular allele of a polymorphic sequence in that the method comprises contacting the nucleic acid sequence in one amplification reaction or separate amplification reaction with a first pair and a second pair of PCR primers, carrying out the amplification reaction with the primer pairs and detecting any amplification product produced from previous step, wherein the presence of amplification product is indicative of the presence of the first allele in the nucleic acid sequence. The first member of the first pair of PCR primers hybridizes to one strand of the nucleic acid sequence and the other member of the first pair of PCR primers hybridizes to the other strand of the nucleic acid sequence on the opposite side of the polymorphic sequence from the side to which the first member of the first pair of primer hybridizes. The first member of the second pair of PCR primers does the same thing as the first member of the first pair of PCR primers. The one of the first pair of PCR primers is (a) complementary at its 3'-terminal nucleotide to a first allele of the polymorphic sequence, (b) non-complementary at its 3' terminal nucleotide to a second allele of the polymorphic sequence, and (c) non-complementary to the nucleic acid sequence at a single nucleotide that is deposited within the five nucleotides adjacent to the 3'-terminal nucleotide, wherein the first pair of primers is capable of amplifying the first allele under appropriate conditions. The one of the second pair of PCR primers has the same features as the

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one of the first pair of PCR primers described above except that the one of the second pair of PCR primers is non complementary to the nucleic acid sequence at one or more nucleotides that are disposed within the five nucleotides adjacent to the 3'- terminal nucleotide, wherein the second pair of primers is capable of amplifying the first allele under appropriate conditions.

The closest prior art is the reference of Newton et al. (US 5,595,890, issued January 21, 1997). Newton et al. disclose a method for detecting the presence or absence of one or more variant nucleotide sequences, but Newton et al. do not disclose the use of PCR pair primers which have the same features as the claimed primers.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J.T.*
May 24, 2004

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/25/04